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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/554,133 | 10/20/2005 | Clifford J Herman | 1332 WO/US | 9352 |

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| EXAMINER | |
|---|---|
| CLAYTOR, DEIRDRE RENEE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

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|---|---|
| 11/13/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/554,133 | HERMAN, CLIFFORD J | |
| | Examiner | Art Unit | |
| | Renee Claytor | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's response filed on 8/30/2007 is acknowledged. Applicants have supplied a new Oath & Declaration that refers to their priority document. Applicants have clarified the claims by supplying one set of claims that are currently pending; therefore, the 35 USC 112 second paragraph rejection is hereby withdrawn as it is clear that there is antecedent basis for claim 6 in claim 1.

Applicant's arguments over the 35 USC 103 rejection are that Midha et al. and Epstein et al. do not disclose or suggest a solution comprising the active in a solvent system that in turn comprises both water and a non-aqueous solvent wherein the concentration of water is less than 50% and that neither reference is concerned with the stability or shelf life of such a solution.

In response, the present claims are drawn to a composition and Midha et al. and Epstein et al. both teach a composition that is obvious over the composition of the present claims. Accordingly, Midha et al. and Epstein et al. teach solutions comprised of the active agent methylphenidate which is dissolved in an aqueous or non-aqueous solvent such as propylene glycol and an organic acid such ascorbic acid and water. Furthermore, as was explained in the previous Office Action, it is obvious to vary and/or optimize the amounts of methylphenidate, organic acid and aqueous and non-aqueous solvents provided in the composition, according to the guidance provided by Midha et al. and Epstein et al. to provide a composition having the desired properties such as the desired concentrations and percentages of each component to formulate an effective methylphenidate solution for administration. It is noted that "[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Applicants further argue that the guidance for preparation of a solution of methylphenidate for administration is not the issue, rather it is for the improved stability and shelf life. It is reiterated that the claims were examined to the extent that they read on a composition and the intended use of the composition is not afforded patentable weight and therefore was not under examination.

In view of Applicant's amendments to the claims, the following modified rejection is given below.

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Midha et al. (US Patent 6,127,385) in view of Epstein et al. (US Pg-Pub 2002/0103162).

Midha et al. teach solutions comprised of methylphenidate that is dissolved in an aqueous or non-aqueous solvent such as propylene glycol and an organic acid such as ascorbic acid (Col. 4, lines 59-63). The solution further contains aromatic oils as

flavoring agents (Col. 4, lines 59-63). Midha et al. further teach that injectable solutions may be prepared using water (Col. 5, lines 21-23).

Midha et al. do not teach the amounts of each component listed, the specific polyols listed in claims 11, 16 and 21 or the glycol listed in claim 22.

Epstein et al. teach pharmaceutical preparations comprised of methylphenidate compounds. It is taught that the preparations may be formulated in a biologically acceptable medium, such as water (solvent) and polyols (non-aqueous solvent; with glycerin, sorbitol and polyethylene glycol listed) and mixtures thereof (meeting the limitations of polyols in claims 11, 16 and 21; paragraph 0250 and 0268). It is further taught that antioxidants may be present in the composition, with citric acid being amongst the possible antioxidants listed (paragraph 0274). Epstein et al. also teach the use of flavoring agents (paragraph 0273).

Furthermore, it is obvious to vary and/or optimize the amounts of methylphenidate, organic acid and aqueous and non-aqueous solvents provided in the composition, according to the guidance provided by Midha et al. and Epstein et al. to provide a composition having the desired properties such as the desired concentrations and percentages of each component to formulate an effective methylphenidate solution for administration. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would be obvious to a person of ordinary skill in the art at the time of the invention to combine the teachings of Midha et al., which teach pharmaceutical solutions comprised of methylphenidate and an organic acid dissolved in propylene glycol and water, with the teachings of Epstein et al. which teach methylphenidate preparations as well and include citric acid as an organic acid that can be used in the composition, as well as a solvent and non-aqueous solvents. One would be motivated to use the citric acid taught by Epstein et al. in the composition of Midha et al. because Midha et al. teach solutions comprised of organic acids and there would be a reasonable expectation of success that citric acid would be effective in the composition as taught by Epstein et al.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER